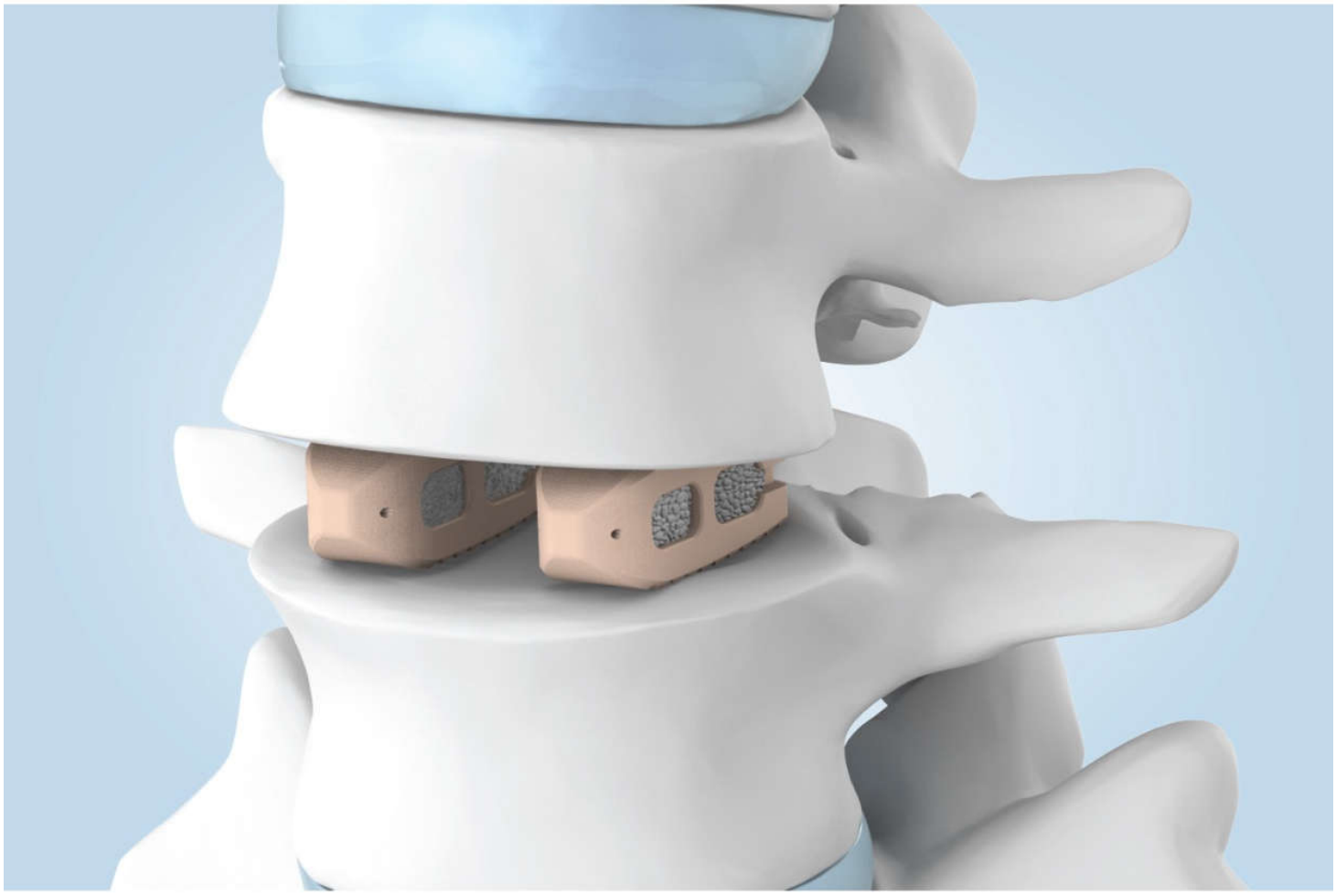
Velofix™ PEEK Lumbar Cage

Surgical Technique



U&I CORPORATION

DISTRACTION OF THE DISC SPACE

Instrument	
CB0108 ~ CB0115	S-DISTRACTOR, lengths 8mm ~ 15mm
SP0002	T-HANDLE

The disc space is sequentially distracted until the appropriate disc space height is obtained and the foraminal opening is restored. This is done by inserting the smallest S-DISTRACTOR, connected to the T-HANDLE, with the flat surface parallel to the endplate.

It is then rotated 90° to distract the space and the T-HANDLE is removed (Fig.3).

Care should be taken in order to avoid over distraction. This process is carried out on alternating sides until the desired height is obtained. The appropriate size of the S-DISTRACTOR is left in the disc space in the distracted position while continued disc space preparation is performed on the opposite side.

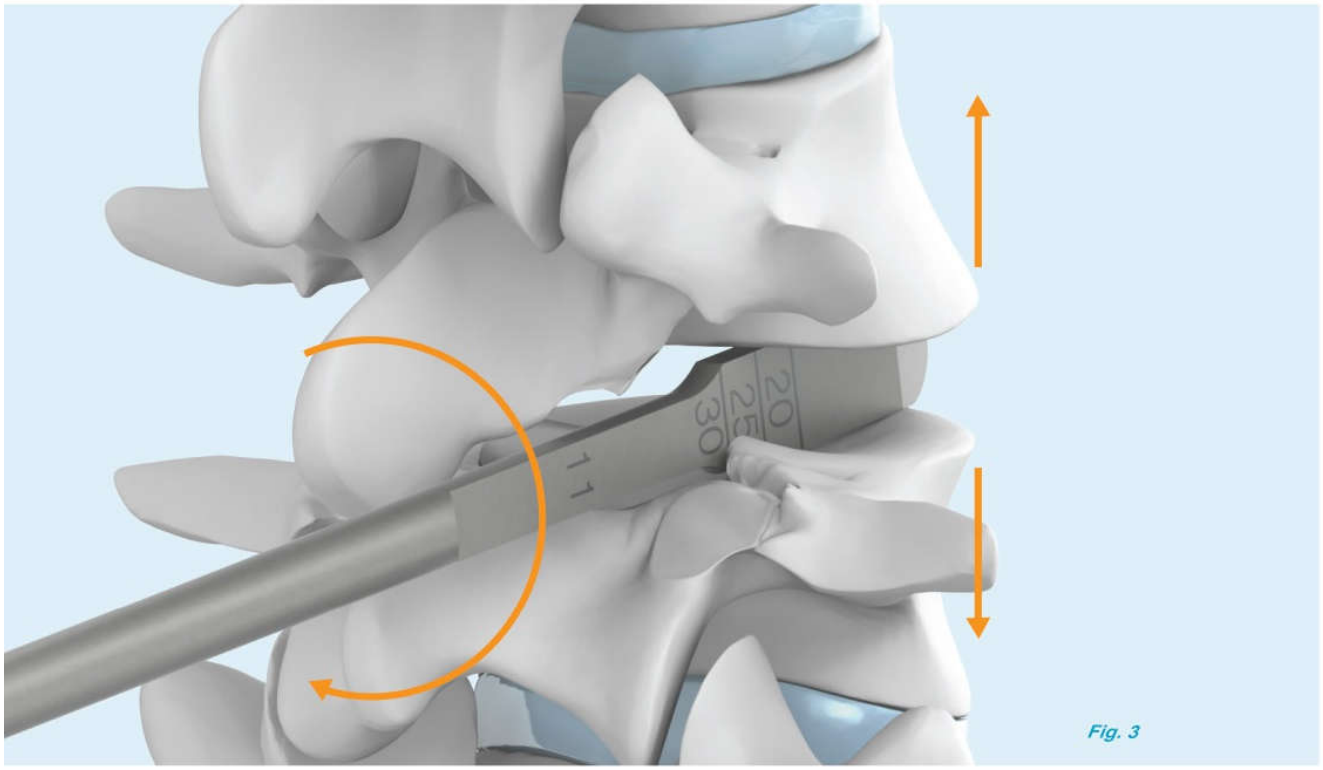


Fig. 3

DISC SPACE PREPARATION

Remove disc material from the intervertebral space using any of the following :
BONE SHAVER or RING CURETTE.

Instrument	
PL0320 ~ PL0360	BONE SHAVER, lengths 8mm ~ 12mm
PL0400	RING CURETTE - STRAIGHT
PL0410	RING CURETTE - RIGHT CURVED
PL0420	RING CURETTER - LEFT CURVED
SP0002	T-HANDLE
PL0440	BONE RASP

OPTION 1) BONE SHAVER

The intended size of BONE SHAVER is inserted into the opposite side of the retracted vertebral body and rotated to remove residual intradiscal material and to create a channel in the dorsal most endplate (Fig.4).

Note : The depth markings on the instrument which can be used to provide an assessment of depth of insertion in the disc space.

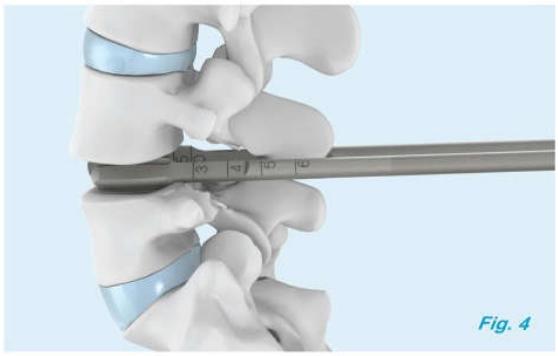


Fig. 4

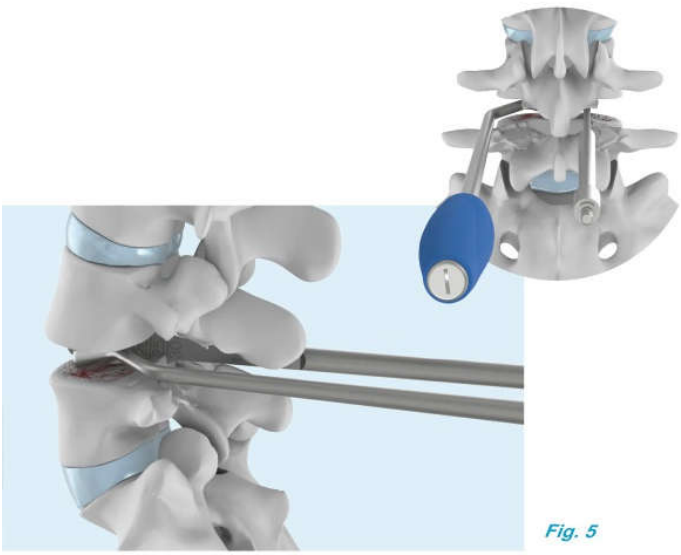


Fig. 5

OPTION 2) RING CURETTE

The remaining soft tissue or cartilaginous endplate coverings are removed from the endplate using the RING CURETTE. A vigorous scraping or curettage of the soft tissue adherent to the endplates is done medially under the midline in the beginning and gradually working laterally in a sweeping motion until both the caudal and cephalad endplates are cleared of the soft tissue (Fig.5).

BONE RASP

When the discectomy is complete, use the BONE RASP to remove the superficial cartilaginous layers of the endplates and to expose the bleeding bone.

DISTRACTION OF THE DISC SPACE

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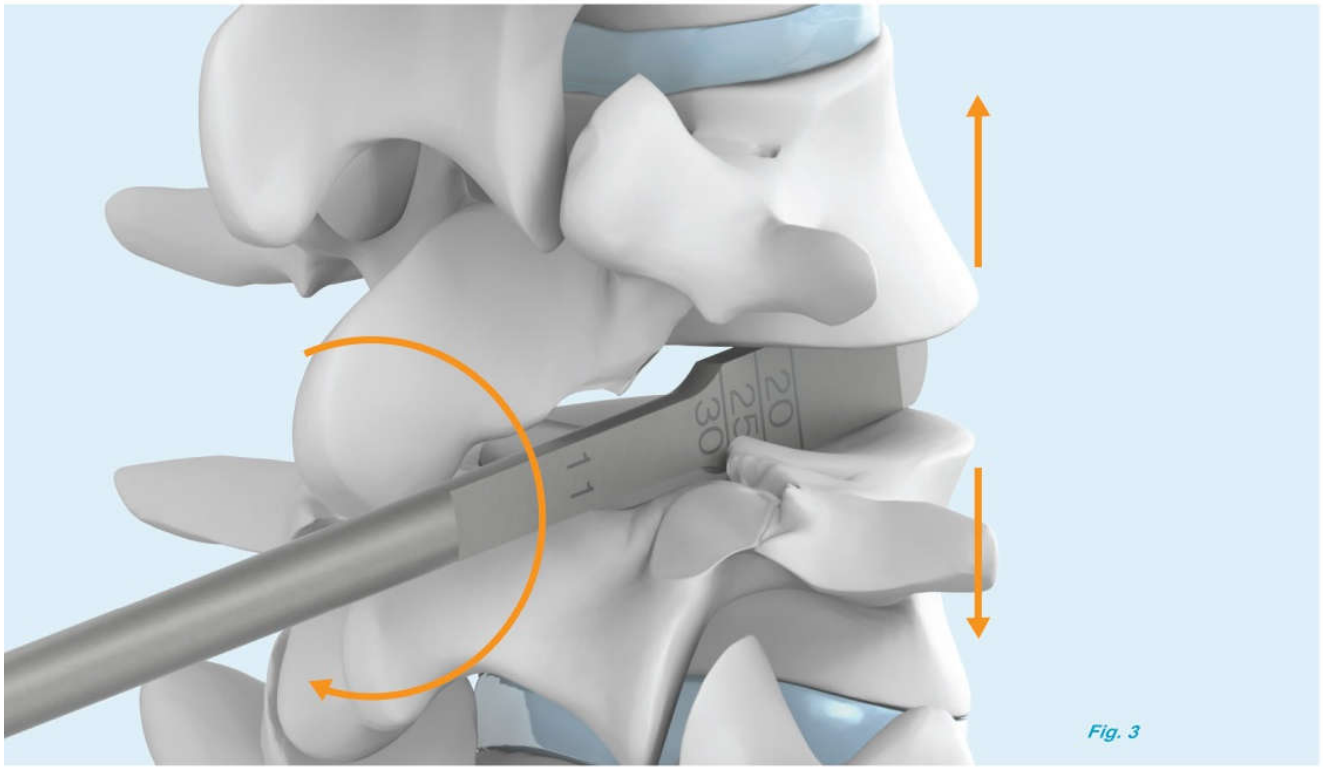

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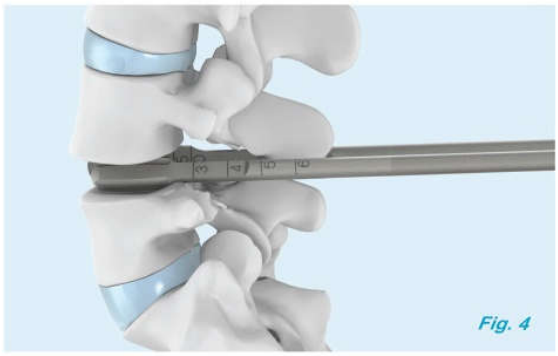
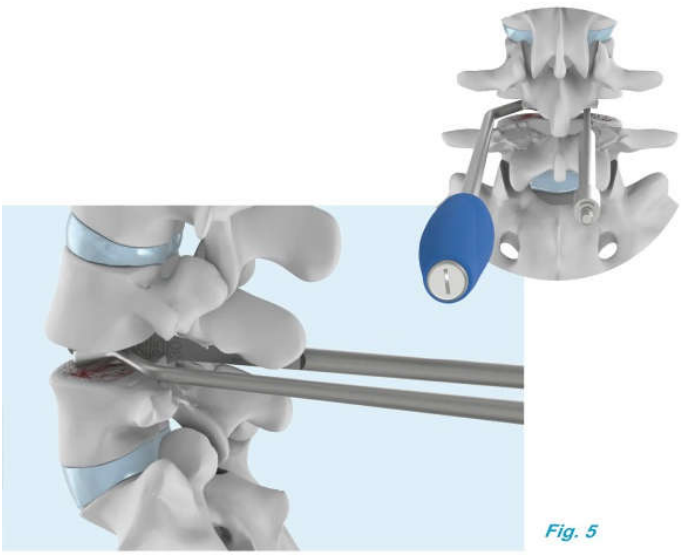


Fig. 4



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BONE RASP

When the discectomy is complete, use the BONE RASP to remove the superficial cartilaginous layers of the endplates and to expose the bleeding bone.

DETERMINATION OF CAGE SIZE

Insert the TRIALs until desired disc space height is established (Fig.6). Use AP and lateral fluoroscopy to confirm proper placement and size.

Instrument	
PL0040 ~ PL0120	TRIAL L22, heights H7~H14, H16
PL0430	SLIDING HAMMER

Fig. 6

Slide the SLIDING HAMMER onto the end of the handle. While holding the TRIAL handle with one hand, apply an upward force to the SLIDING HAMMER with the other hand ❶. Repeat this process until the TRIAL head is removed.
Remove the SLIDING HAMMER from the TRIAL handle by pushing on the end of the SLIDE HAMMER ❷.

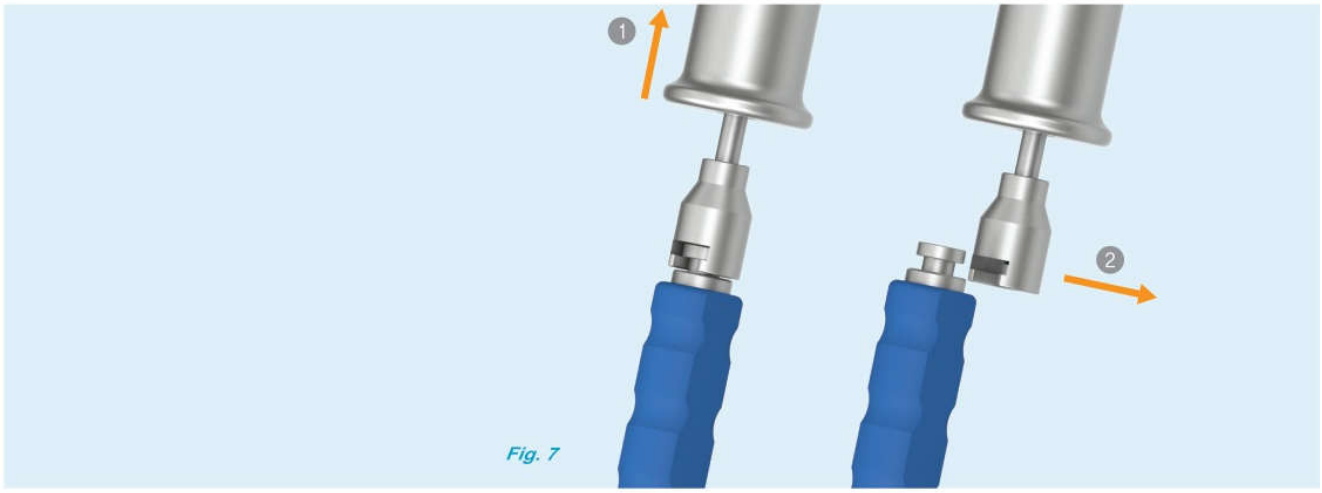


Fig. 7

CAGE INSERTION PREPARATION

Instrument	
PL0010	CAGE INSERTION SHAFT
PL0011	CAGE INSERTION SHAFT WITH T-HANDLE
PL0020	FIXATION BOLT

Screw the FIXATION BOLT into the CAGE INSERTION SHAFT ❶.
Insert the anti-rotation blocks of the CAGE INSERTION SHAFT in the selected cage ❷.
Perform the final screw tightening by rotating the FIXATION BOLT.

Note : The CAGE INSERTION SHAFT WITH T-HANDLE can be used instead of CAGE INSERTION SHAFT.

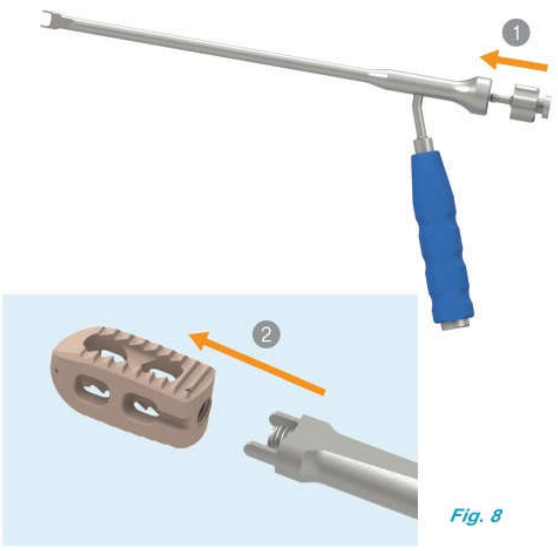


Fig. 8

Fig. 9

BONE PACKING

Instrument	
CB0931	S PACKING PLATFORM
PL0450	BONE PACKING BAR

The implant should be packed with bone grafting material. Typically, cancellous bone taken from the iliac crest is used. The S PACKING PLATFORM is used to hold the cage. The graft is carefully compacted using the BONE PACKING BAR (Fig.9).

CAGE INSERTION

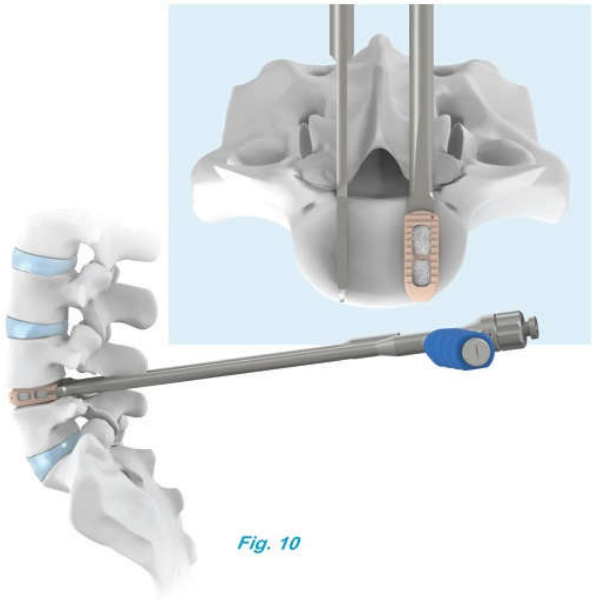


Fig. 10

Insert the first cage with the "graft" sides parallel to the vertebral plates. The cage should be inserted such that its posterior edge is driven approximately 3~4mm beyond the posterior wall of the vertebral body (Fig.10).

Note : Check the position of the cages with the fluoroscopy (Fig.11).

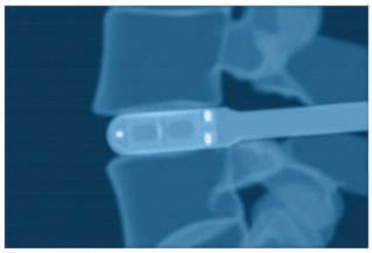


Fig. 11

SECOND CAGE INSERTION

After removing the S-DISTRACTOR, insert a second cage of the same height as laterally as possible, leaving a clear gap between the first cage. Ensure that the first cage is not displaced during the insertion of the second cage (Fig.12).

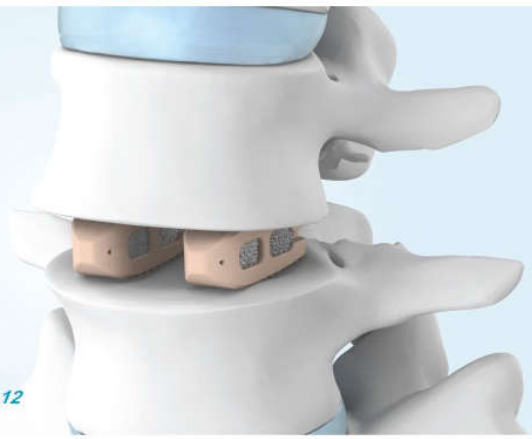


Fig. 12

SUPPLEMENTAL FIXATION

Velofix™ PEEK Lumbar cage is intended to be used with U&i supplemental fixation, e.g. ANAX™ 5.5, OPTIMA™ or PERFIX™ SPINAL SYSTEMs to apply the adequate compression.

IMPLANT REMOVAL PROCEDURE

Instrument	
PL0010	CAGE INSERTION SHAFT
PL0011	CAGE INSERTION SHAFT WITH T-HANDLE
PL0020	FIXATION BOLT
PL0430	SLIDING HAMMER

Velofix™ PEEK Lumbar cage may be removed by attaching the CAGE INSERTION SHAFT and FIXATION BOLT to the inserted cages and removing them from the disc space. If greater force is needed, attach the SLIDING HAMMER on rear of the FIXATION BOLT. Use of SLIDING HAMMER is identical to that of the TRIAL removal (Fig.13).

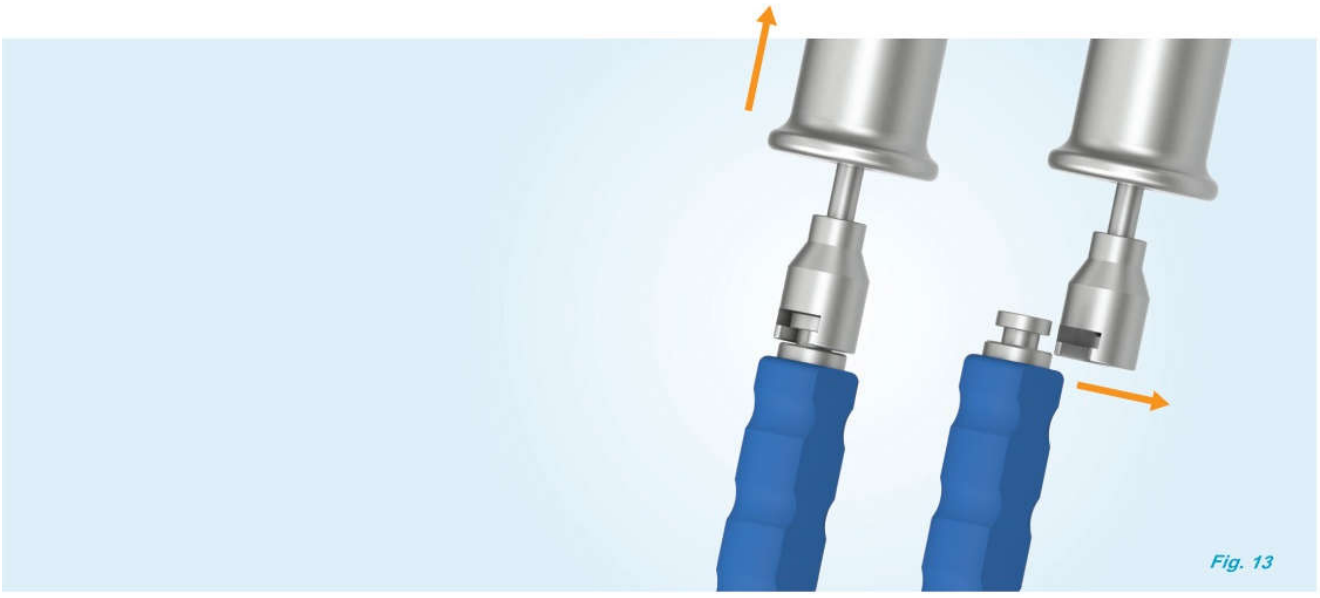


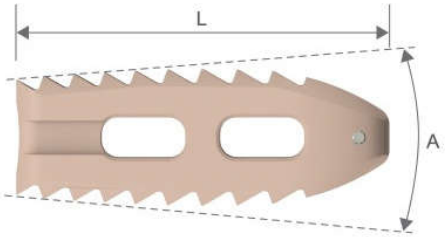
Fig. 13

Ordering Information

Implant (Single-Use Only)

Cat. No.	L (mm)	A (°)	W (mm)	H (mm)
PL1007	22	0	9	7
PL1008	22	0	9	8
PL1009	22	0	9	9
PL1010	22	0	9	10
PL1011	22	0	10	11
PL1012	22	0	10	12
PL1013	22	0	10	13
PL1014	22	0	11	14
PL1016	22	0	11	16
PL1408	22	4	9	8
PL1409	22	4	9	9
PL1410	22	4	9	10
PL1411	22	4	10	11
PL1412	22	4	10	12
PL1413	22	4	10	13
PL1414	22	4	11	14
PL1416	22	4	11	16
PL1809	22	8	9	9
PL1810	22	8	9	10
PL1811	22	8	10	11
PL1812	22	8	10	12
PL1813	22	8	10	13
PL1814	22	8	11	14
PL1816	22	8	11	16

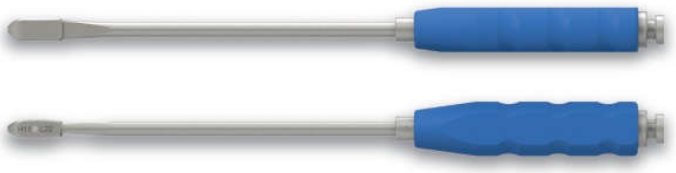
Cat. No.	L (mm)	A (°)	W (mm)	H (mm)
PL2007	26	0	9	7
PL2008	26	0	9	8
PL2009	26	0	9	9
PL2010	26	0	9	10
PL2011	26	0	10	11
PL2012	26	0	10	12
PL2013	26	0	10	13
PL2014	26	0	11	14
PL2016	26	0	11	16
PL2408	26	4	9	8
PL2409	26	4	9	9
PL2410	26	4	9	10
PL2411	26	4	10	11
PL2412	26	4	10	12
PL2413	26	4	10	13
PL2414	26	4	11	14
PL2416	26	4	11	16
PL2809	26	8	9	9
PL2810	26	8	9	10
PL2811	26	8	10	11
PL2812	26	8	10	12
PL2813	26	8	10	13
PL2814	26	8	11	14
PL2816	26	8	11	16
PL3007	30	0	9	7
PL3008	30	0	9	8
PL3009	30	0	9	9
PL3010	30	0	9	10
PL3011	30	0	10	11
PL3012	30	0	10	12
PL3013	30	0	10	13
PL3014	30	0	11	14
PL3016	30	0	11	16



Instruments

PEEK TRIAL

Cat. No.	H (mm)	L (mm)
PL0040	7	22
PL0050	8	22
PL0060	9	22
PL0070	10	22
PL0080	11	22
PL0090	12	22
PL0100	13	22
PL0110	14	22
PL0120	16	22



DISTRACTOR

Cat. No.	size (mm)
CB0108	8
CB0109	9
CB0110	10
CB0111	11
CB0112	12
CB0113	13
CB0114	14
CB0115	15

PL0450

BONE PACKING BAR

CB0931

S PACKING PLATFORM

PL0440
BONE RASP

PL0400
RING CURETTE - STRAIGHT

PL0410
RING CURETTE - RIGHT CURVED

PL0412
RING CURETTE - LEFT CURVED

PL0320
BONE SHAVER - 8mm

PL0340
BONE SHAVER - 10mm

PL0360
BONE SHAVER - 12mm

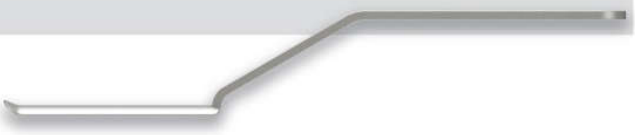
PL0010
CAGE INSERTION SHAFT

PL0011
CAGE INSERTION SHAFT WITH T-HANDLE

PL0020
FIXATION BOLT

PL0430
SLIDING HAMMER

PL0460
NERVE RETRACTOR



Important Information on the Velofix™ PEEK Lumbar Cage

PURPOSE
The Velofix™ PEEK Lumbar Cage implanted via the posterior approach is intended to facilitate interbody arthrodesis.

DESCRIPTION
The Velofix™ PEEK Lumbar Cage allows restoration of the disc height and natural curvature. Nerve root decompression is also achieved by opening the neural foramen. The cages are available in several sizes with implant selection based on each individual clinical case.

MATERIALS
The Velofix™ PEEK Lumbar Cage implant is manufactured from PEEK-OPTIMA LT1(ASTM F2026) and three radiopaque markers are made of TANTALUM which complied with ASTM F560.

INDICATIONS
The Velofix™ PEEK Lumbar Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease(DDD) at one or two levels for L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as back pain of discongenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended to be used with supplemental fixation.

COMBINATION SYSTEM
Velofix™ PEEK Lumbar Cage is used with posterior lumbar fixation system.(screws, hooks, transverse links, connectors, etc.)

IMPORTANT NOTE
The users of the Velofix™ PEEK Lumbar Cage acknowledge that they have read and agreed to the conditions in this insert, which are considered to be contractual.

GENERAL CONDITIONS OF USE
- The implants must be implanted only by physicians having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with the surgical and medical indications, the potential risks and limitations related to this type of surgery, the contra-indications, possible adverse events, and precautions defined and in the knowledge of the nature and metallic, metallurgic and biological characteristics of the implants to be used.
- It is recommended that the Velofix™ Systems should not be used together with implants from a different source, a different manufacturer, or made from a different material. If this should occur, U&i decline all responsibility.
- Under no circumstances may the implants be re-used; although the device may appear intact on removal, internal modifications due to the stresses and strains placed on it, or small defects may exist, which may lead to the fracture of the implant.

CONTRAINDICATIONS
- The Velofix™ should not be implanted in patients with an active infection at the operative site.
- Any active or suspected latent infection in or about the spine.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fusion to the devices.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fusion of the device or to failure of the device itself.
- Recent infection, fever, or leukocytosis.
- Open wounds
- Metal sensitivity, documented or suspected
- Patient having inadequate tissue coverage over the operative site.
- Pregnancy
- Excessive local inflammation
- Prior fusion at the level(s) to be treated.
- Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count(WBC), or marked left shift in the WBC differential count.

POSSIBLE ADVERSE EVENTS
- Late bone grafting or no visible fusion mass and pseudarthrosis
- Neurological complications, paralysis, soft tissue lesions, pain due to the surgical procedure, the breakage, the deformation and/or migration of the implant
- Superficial or deep-set infection and inflammatory phenomena
- Allergic reaction to the PEEK or TANTALUM materials
- Reduction in bone density due to a different distribution of mechanical stresses
- Pain and abnormal sensations due to hardware bulkiness
- Neurological and spinal dura mater lesions from surgical trauma
- Bursitis
- Presence of microparticles around the implants
- Growth of the fused vertebrae is altered
- Partial loss of the degree of correction achieved during surgery
- Modification of spinal curvature and stiffness of the vertebral column

The above list of side effect is not exhaustive. These side effects can sometimes necessitate further surgical treatment.

PRECAUTIONS
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device.
- Safety and effectiveness have not been established for patients with the following conditions: previous fusion attempt at the involved level(s), spondylolisthesis greater than Grade I, three or more levels to be fused, concomitant conditions requiring steroids, systemic or terminal illness, active drug abuse, gross obesity, severe osteoporotic conditions and pregnancy.
- In some cases, progression of degenerative disease may be so advanced at the time of implantation that they may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the interbody fusion require detailed knowledge of spinal surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre-/post-operative patient management are considerations essential to a successful surgical outcome.
- Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic or polymer implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
- Appropriate selection, placement and fusion of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biological, biomechanical and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life.
  Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants.
- Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- Check if implant type is appropriate for use in intended region of spine
- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- Patients with previous spine surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

WARNING
- Benefit of spinal fusions utilizing any interbody fusion system has not been adequately established in patients with stable spines.
- Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fusion, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged. Reusing of the implant can cause early fracture, deformation and patient's infection.
- Interbody fusion devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.
- Mixing Metal: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Interbody fusion devices which come into contact with other metal objects, must be made from like or compatible metals.
- Because different manufactures employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, the Velofix™ System should not be used in conjunction with components from any other manufacture's spinal system and instruments. Any such use will negate the responsibility of U&I Corporation for the performance of the resulting mixed component implant.
- Any decision by a physician to remove the interbody fusion device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Implant removal should be followed by adequate postoperative management to avoid fracture.

PREOPERATIVE, INTRAOPERATIVE, POSTOPERATIVE

IMPLANT SELECTION
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE
- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
- An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.

POSTOPERATIVE
The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.
- Patients are required to wear a spinal brace which limits flexion in the lumbar region.
- Chairback braces are not recommended because they afford insufficient immobilization.
- Patients are allowed to get out of bed only after they are fitted the brace.
- Establishment of a postoperative rehabilitation schedule that includes an exercise program for the patient is recommended.

PACKAGING, LABELING AND STORAGE
- The implants are supplied clean and NON-STERILE. They must be sterilized prior to use(see below).
- The implants are delivered in packages. These must be intact at the time of receipt. All the legal information required for this type of implant is given in the labeling of each package.
- Implants may be delivered as a complete set, in specially designed trays or in boxes which can be sterilized directly.
- Use care in handling and storage of implant components. Cutting, sharply bending or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if the instruments or implants have been damaged during storage or prior procedures.
- Damaged packages or products should not be used, and should be returned to U&i.

CLEANING PROCEDURES

Preparation of Cleaning Agents
- Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.

Manual Cleaning Procedure
- Use the neutral pH enzyme soaking solution that has been prepared.
- Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
  Note: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
- Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
- Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
- Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
- Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
- Repeat Steps 5 and 6 with freshly prepared cleaning solution.
- Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.

Automated Cleaning Procedure
- Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.
  - CAUTION : Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
  - Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
  - Verify that the instruments are in operation condition.

STERILIZATION PROCEDURES
- Ultrasonic clean for five minutes using distilled water CAUTION : Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Verify that the instruments are in operation condition.
- Sterilization: Recommended method to achieve a degree of sterility equal to at least 10^{-6}.
  Sterilize by the autoclaving procedure regularly used in the hospital.

Table 1. Sterilization parameters

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Gravity	270°F(132℃)	20 minutes	20 minutes
Steam	Pre-Vacuum	270°F(132℃)	4 minutes	20 minutes

- Gravity cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).
- Users should only use sterilizer accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared for use in their markets.

PHYSICIAN NOTE
Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION
- Federal law(USA) restricts these devices to sale by or on the order of a physician.
- FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

GUARANTEE
The guarantee is only applicable if the device is used in accordance with normal conditions as defined in these instructions and in conformity with the recommended surgical technique.
The use-life of all instruments used with Velofix™ PEEK Lumbar Cage is 5 years.

FURTHER INFORMATION
In case of complaint, or for supplementary information, or further directions for use of this system, please see the address on this page.

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